05/18/2007

Attorney's Docket No.: 20214-002US1 / SEN-A0302P-U

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Yoshida et al.

Art Unit : 1614

Serial No.: 10/561,298

Examiner: Unknown

Filed

: December 20, 2005

Conf. No.: 1652

Title

: HISTONE DEACETYLASE INHIBITOR AND PROCESS FOR PRODUCING

THE SAME

## Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

# **TRANSMITTAL**

The following correspondence relating to this application is enclosed for filing:

- Information Disclosure Statement (1 page); 1.
- 2. Form PTO-1449 (4 pages);
- Copies of Cited References (74 references); and 3.
- 4. A Return Postcard.

Please date stamp and return the enclosed postcard. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Elizabeth N. Kaytor, Ph.D.

Reg. No. 53,103

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Lisa M. Becker

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10561298 - GAU: 1654

Attorney's Docket No.: 20214-002US1 / SEN-A0302P-US

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# MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# INFORMATION DISCLOSURE STATEMENT

Applicants request consideration of the references listed on the attached PTO-1449 form. Under 37 C.F.R. § 1.98 (a)(2)(ii), only copies of foreign patent documents and/or non-patent literature are enclosed. Copies of any listed U.S. patents or U.S. patent application publications can be provided upon request.

This statement is being filed before the receipt of a first Office Action on the merits. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: May 16, 2007

Elizabeth N. Kaytor, Ph.D

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Sheet <u>1</u> of <u>4</u>

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U.S. Department of Commerce Patent and Trademark Office Attorney's Docket No. Application No. 20214-002US1 10/561,298

# Information Disclosure Statement by Applicant

(Use several sheets if necessary)

(37 CFR §1.98(b))

2021- 002001	10/501,250
Applicant Yoshida et al.	
Filing Date December 20, 2005	Group Art Unit 1614

	U.S. Patent Documents						
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	5,922,837	07/13/99	Meinke et al.			
	AB	6,399,568	06/04/02	Nishino et al.			
	AC	2002/0120099	08/29/02	Nishino et al.			
	AD	2003/0078369	04/24/03	Meinke et al.			

	Foreig	n Patent Doc	uments or P	ublished Foreign	Patent A	Application	ns	
Examiner	Desig.	Document	Publication	Country or			Trans	lation
Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No
	AE	2 317 003	08/29/00	CA				
	AF	1 010 705	06/21/00	EP				
	AG	1 174 438	01/23/02	EP				
	AH	11-130795	05/18/99	JР			Abst.	
	AI	2000-256397	09/19/00	JP			Abst.	
	AJ	2002-527449	08/27/02	JP			Abst.	
	AK	2001-316283	11/13/01	JP			Abst.	
	AL	2003-505417	02/12/03	JP			Abst.	
	AM	WO 00/21979	04/20/00	WIPO				
	AN	WO 00/52033	09/08/00	WIPO			Abst.	
	AO	WO 01/07042	02/01/01	WIPO				
	AP	WO 03/57722	07/17/03	WIPO				
	AQ	WO 03/70754	08/28/03	WIPO			Abst.	

	Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner	Desig.		
Initial	ID	Document	
	AR	Bernhard et al., "Interaction between dexamethasone and butyrate in apoptosis induction: non-additive in thymocytes and synergistic in a T cell-derived leukemia cell line," Cell Death Diff., 1999, 6:609-617	
	AS	Boivin et al., "Antineoplastic action of 5-aza-2'-deoxycytidine and phenylbutyrate on human lung carcinoma cells," Anti-Cancer Drugs, 2002, 13:869-874	
	AT	Cameron et al., "Synergy of demethylation and histone deacetylase inhibition in the re-expression of genes silenced in cancer," Nature Genet., 1999, 21:103-107	

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10561298 - GAU: 1654

Sheet <u>2</u> of <u>4</u>

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 20214-002US1	Application No. 10/561,298
	closure Statement	Applicant Yoshida et al.	
(Use several sheets if necessary) (37 CFR §1.98(b))		Filing Date December 20, 2005	Group Art Unit 1614

F		ocuments (include Author, Title, Date, and Place of Publication)
Examiner Initial	Desig. ID	Document
iiiiidi	AU	Chen et al., "Reactivation of silenced, virally transduced genes by inhibitors of histone deacetylase,"
		Proc. Natl. Acad. Sci. USA, 1997, 94:5798-5803
	AV	Coffey et al., "The Histone Deacetylase Inhibitor, CBHA, Inhibits Growth of Human Neuroblastom Xenografts in Vivo, Alone and Synergistically with All-Trans Retinoic Acid," Cancer Res., 2001, 61:3591-3594
	AW	Colletti et al., "Design and synthesis of histone deacetylase inhibitors: the development of apicidin transition state analogs," Tetrahedron Lett., 2000, 41:7837-7841
	AX	Colletti et al., "Broad Spectrum Antiprotozoal Agents that Inhibit Histone Deacetylase: Structure-Activity Relationships of Apicidin. Part 2," <u>Bioorg. Med. Chem. Lett.</u> , 2001, 11:113-117
	AY	Darkin-Rattray et al., "Apicidin: A novel antiprotozoal agent that inhibits parasite histone deacetylase," Proc. Natl. Acad. Sci. USA, 1996, 93:13143-13147
	AZ	De Schepper et al., "Inhibition of Histone Deacetylases by Chlamydocin Induces Apoptosis and Proteasome-Mediated Degradation of Survivin," J. Pharmacol. Exp. Ther., 2003, 304(2):881-888
	AAA	Dhordain et al., "Corepressor SMRT binds the BTB/POZ repressing domain of the LAZ3/BCL6 oncoprotein," Proc. Natl. Acad. Sci. USA, 1997, 94:10762-10767
	ABB	Dion et al., "Amplification of Recombinant Adenoviral Transgene Products Occurs by Inhibition of Histone Deacetylase," Virology, 1997, 231:201-209
	ACC	Ferrara et al., "Histone Deacetylase-targeted Treatment Restores Retinoic Acid Signaling and Differentiation in Acute Myeloid Leukemia," Cancer Res., 2001, 61:2-7
	ADD	Finnin et al., "Structures of a histone deacetylase homologue bound to the TSA and SAHA inhibitors," Nature, 1999, 401:188-193
	AEE	Fischle et al., "A New Family of Human Histone Deacetylases Related to Saccharomyces cerevisia HDA1p," J. Biol. Chem., 1999, 274(17):11713-11720
	AFF	Frey et al., "Trifluoromethyl Ketones as Inhibitors of Histone Deacetylase," <u>Bioorg. Med. Chem.</u> Lett., 2002, 12:3443-3447
	AGG	Furumai et al., "Potent histone deacetylase inhibitors built from trichostatin A and cyclic tetrapeptide antibiotics including trapoxin," Proc. Natl. Acad. Sci. USA, 2001, 98(1):87-92
	АНН	Furumai et al., "FK228 (Depsipeptide) as a Natural Prodrug That Inhibits Class I Histone Deacetylases," Cancer Res., 2002, 62:4916-4921
	AII	Göttlicher et al., "Valproic acid defines a novel class of HDAC inhibitors inducing differentiation of transformed cells," EMBO J., 2001, 20(24):6969-6978
	AJJ	Grignani et al., "Fusion proteins of the retinoic acid receptor-α recruit histone deacetylase in promyelocytic leukaemia," Nature, 1998, 391:815-818
	AKK	He et al., "Distinct interactions of PML-RARα and PLZF-RARα with co-repressors determine differential responses to RA in APL," Nature Genet., 1998, 18:126-135
	ALL	Hoshi et al., "Activation of a Ca <sup>2+</sup> -inhibitable Protein Kinase That Phosphorylates Microtubule-associated Protein 2 in Vitro by Growth Factors, Phorbol Esters, and Serum in Quiescent Cultured Human Fibroblasts," J. Biol. Chem., 1988, 263(11):5396-5401
	AMM	Hoshikawa et al., "Expression of Differentiation-related Markers in Teratocarcinoma Cells via Histone Hyperacetylation by Trichostatin A," Agric. Biol. Chem., 1991, 55(6):1491-1495
-	ANN	Hubbert et al., "HDAC6 is a microtubule-associated deacetylase," Nature, 2002, 417:455-458
	AOO	Inokoshi et al., "Neuronal Differentiation of Neuro 2a Cells by Inhibitors of Cell Cycle Progression Trichostatin A and Butyrolactone I," Biochem. Biophys. Res. Commun., 1999, 256(2):372-376

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if no next communication to applicant.	t in conformance and not considered. Include copy of this form with

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Sheet <u>3</u> of <u>4</u>

Substitute Form PTO-1449 U.S. Department of Commerce Patent and Trademark Office		Attorney's Docket No. 20214-002US1	Application No. 10/561,298
	closure Statement	Applicant Yoshida et al.	
(Use several sheets if necessary) (37 CFR §1.98(b))		Filing Date December 20, 2005	Group Art Unit 1614

	Other D	ocuments (include Author, Title, Date, and Place of Publication)
Examiner Initial	Desig. ID	Document
	APP	Ito et al., "p300/CBP-mediated p53 acetylation is commonly induced by p53-activating agents and inhibited by MDM2," EMBO J., 2001, 20(6):1331-1340
	AQQ	Jose et al., "Toward an HDAC6 inhibitor: synthesis and conformational analysis of cyclic hexapeptide hydroxamic acid designed from α-tubulin sequence," <u>Bioorg. Med. Chem.</u> , 2004, 12:1351-1356
	ARR	Juan et al., "Histone Deacetylases Specifically Down-regulate p53-dependent Gene Activation," <u>J.</u> <u>Biol. Chem.</u> , 2000, 275(27):20436-20443
	ASS	Kim et al., "Histone deacetylases induce angiogenesis by negative regulation of tumor suppressor genes," Nature Med., 2001, 7(4):437-443
	ATT	Kim et al., "Oxamflatin is a novel antitumor compound that inhibits mammalian histone deacetylase," Oncogene, 1999, 18:2461-2470
	AUU	Komatsu et al., "Cyclic Hydroxamic-acid-containing Peptide 31, a Potent Synthetic Histone Deacetylase Inhibitor with Antitumor Activity," Cancer Res., 2001, 61:4459-4466
	AVV	Kwon et al., "Histone deacetylase inhibitor FK228 inhibits tumor angiogenesis," Int. J. Cancer, 2002, 97:290-296
	AWW	Li et al., "Causal Relationship between the Loss of RUNX3 Expression and Gastric Cancer," Cell, 2002, 109:113-124
	AXX	Lin et al., "Role of the histone deacetylase complex in acute promyelocytic leukaemia," Nature, 1998, 391:811-814
	AYY	Liu et al., "Histone Deacetylase Inhibitor Up-Regulates RECK to Inhibit MMP-2 Activation and Cancer Cell Invasion," Cancer Res., 2003, 63:3069-3072
	AZZ	Marks et al., "Histone Deacetylase Inhibitors: Inducers of Differentiation or Apoptosis of Transformed Cells," J. Natl. Cancer Inst., 2000, 92(15):1210-1216
	AAAA	Matsuyama et al., "In vivo destabilization of dynamic microtubules by HDAC6-mediated deacetylation," EMBO J., 2002, 21(24):6820-6831
	ABBB	McCampbell et al., "Histone deacetylase inhibitors reduce polyglutamine toxicity," Proc. Natl. Acad. Sci. USA, 2001, 98(26):15179-15184
	ACCC	McKinsey et al., "Signal-dependent nuclear export of a histone deacetylase regulates muscle differentiation," Nature, 2000, 408:106-111
	ADDD	Meinke et al., "Synthesis of side chain modified apicidin derivatives: potent mechanism-based histone deacetylase inhibitors," Tetrahedron Lett., 2000, 41:7831-7835
	AEEE	Minucci et al., "A histone deacetylase inhibitor potentiates retinoid receptor action in embryonal carcinoma cells," Proc. Natl. Acad. Sci. USA, 1997, 94:11295-11300
	AFFF	Mori et al., "FR235222, a Fungal Metabolite, is a Novel Immunosuppressant that Inhibits Mammalian Histone Deacetylase (HDAC). 1. Taxonomy, Fermentation, Isolation and Biological Activities," J. Antibiot., 2003, 56(2):72-79
	AGGG	Munster et al., "The Histone Deacetylase Inhibitor Suberoylanilide Hydroxamic Acid Induces Differentiation of Human Breast Cancer Cells," Cancer Res., 2001, 61:8492-8497
	АННН	Nakajima et al., "FR901228, a Potent Antitumor Antibiotic, Is a Novel Histone Deacetylase Inhibitor," Exp. Cell Res., 1998, 241:126-133
	AIII	Nan et al., "Transcriptional repression by the methyl-CpG-binding protein MeCP2 involves a histone deacetylase complex," Nature, 1998, 393:386-389

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Sheet <u>4</u> of <u>4</u>

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Information Disclosure Statement by Applicant (Use several sheets if necessary)  (37 CFR §1.98(b))		Applicant Yoshida et al.	
		Filing Date December 20, 2005	Group Art Unit 1614

Other Documents (include Author, Title, Date, and Place of Publication)			
Examiner Initial	Desig. ID	Document	
	AJJJ	Nishino et al., "Synthesis and histone deacetylase inhibitory activity of cyclic tetrapeptides containing a retrohydroxamate as zinc ligand," Bioorg. Med. Chem. Lett., 2004, 14:2427-2431	
	AKKK	Parti et al. "Complete remission through blast cell differentiation in PLTE/PAPor positive acute	
	ALLL	Primeau et al., "Synergistic antineoplastic action of DNA methylation inhibitor 5-AZA-2'-deoxycytidine and histone deacetylase inhibitor depsipeptide on human breast carcinoma cells," <u>Int.</u> <u>J. Cancer</u> , 2003, 103:177-184	
	AMMM	and Prevents 1 GF-B <sub>1</sub> -induced Fibrogenesis in Skin Fibroblasts, <u>Exp. Cell. Res.</u> , 2002, 278:184-197	
	ANNN	Ryu et al., "Histone deacetylase inhibitors prevent oxidative neuronal death independent of expanded polyglutamine repeats via an Sp1-dependent pathway," <u>Proc. Natl. Acad. Sci. USA</u> , 2003, 100(7):4281-4286	
	A000	Saito et al., "A synthetic inhibitor of histone deacetylase, MS-27-275, with marked in vivo antitumor activity against human tumors," Proc. Natl. Acad. Sci. USA, 1999, 96:4592-4597	
	APPP	Scherer et al., "Studies on the Propagation in Vitro of Poliomyelitis Viruses. IV. Viral Multiplication in a Stable Strain of Human Malignant Epithelial Cells (Strain HeLa) Derived from an Epidermoid Carcinoma of the Cervix," J. Exp. Med., 1953, 97:695-710	
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	ARRR	Steffan et al., "Histone deacetylase inhibitors arrest polyglutamine-dependent neurodegeneration in <i>Drosophila</i> ," Nature, 2001, 413:739-743	
	ASSS	Verdel and Khochbin, "Identification of a New Family of Higher Eukaryotic Histone Deacetylases. Coordinate Expression of Differentiation-dependent Dhromatin Modifiers," J. Biol. Chem., 1999, 274(4):2440-2445	
A TTT Ver		Verdel et al., "Active maintenance of mHDA2/mHDAC6 histone-deacetylase in the cytoplasm," Curr. Biol., 2000, 10:747-749	
	AUUU	Wang et al., "Inhibitors of Histone Deacetylase Relieve ETO-mediated Repression and Induce Differentiation of AML1-ETO Leukemia Cells," Cancer Res., 1999, 59:2766-2769	
	AVVV	Yang et al., "Isolation and Characterization of cDNAs Corresponding to an Additional Member of the Human Histone Deacetylase Gene Family," J. Biol. Chem., 1997, 272(44):28001-28007	
	AWWW	Yoshida et al., "Effects of Trichostatins on Differentiation of Murine Erythroleukemia Cells," Cancer Res., 1987, 47:3688-3691	
	AXXX	Vachide at al. "Potent and Specific Inhibition of Mammalian Historia Description Both in Vive and	
	AYYY	Yoshida et al., "Trichostatin A and trapoxin: novel chemical probes for the role of histone acetylation in chromatin structure and function," <u>BioEssays</u> , 1995, 17(5):423-430	
	AZZZ	Zhang et al., "HDAC-6 interacts with and deacetylates tubulin and microtubules in vivo," EMBO J., 2003, 22(5):1168-1179	

Examiner Signature	Date Considered			
/Thomas Heard/	02/09/2009			
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